

Exhibit 12

From: David Bonilla
Sent: Monday, November 19, 2018 1:00 PM
To: ORA PHARM1 RECALLS
Cc: Constance Truemper; Christopher Unger
Subject: Re: Request for Conference Call to discuss NDEA

LCDR Dellarese Herbert,

Thanks for the communication. As indicated on our call last week Teva is prepared to Recall the product and we are finalizing the details to do so. As indicated we were preparing to send an updated Field Alert Report today.

Sincerely,
David

David Bonilla
Assoc Director Commercial Quality & Compliance
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Sent from my iPhone

On Nov 19, 2018, at 7:48 AM, ORA PHARM1 RECALLS <orapharm1recalls@fda.hhs.gov> wrote:

Good Morning Connie,

Based on the agency's testing of Teva's valsartan finished drug products to-date, we recommend Teva conduct a voluntary recall of the valsartan products containing NDEA listed below:

Product Description	NDC	Lot Number	NDEA
Amlodipine and Valsartan 320mg/10mg		0093-7693-56 26X053	0.085 ppm
Amlodipine, Valsartan and Hydrochlorothiazide 10mg/320mg/25mg		0093-7809-56 22X045	0.094 ppm

As discussed during the meeting, this requires press and CDER would like an opportunity to review your public notification prior to its issuance on Monday, November 19, 2018. Please send me the draft copies of the Press Release and Customer Notification Letter and Stock Response Form.

Thanks!

LCDR Dellarese Herbert, Recall Coordinator Pharma Division I & IV
215-717-3747

From: Constance Truemper [<mailto:Constance.Truemper@actavis.com>]

Sent: Thursday, November 15, 2018 10:28 AM

To: Herbert, Dellarese L <Dellarese.Herbert@fda.hhs.gov>; Christopher Unger <Christopher.Unger@tevapharm.com>;
David Bonilla <David.Bonilla@tevapharm.com>; ORA PHARM1 RECALLS <orapharm1recalls@fda.hhs.gov>

Subject: RE: Request for Conference Call to discuss NDEA

Hello Della

I am on a conference call with the team and we will respond soon.

Connie T Truemper

Mgr Quality Professional

<image003.png>

Tel: 1-973-658-1839 **Cell:** 1-908-303-4319

Constance.Truemper@actavis.com www.tevapharm.com

<image005.jpg>

From: Herbert, Dellarese L [<mailto:Dellarese.Herbert@fda.hhs.gov>]

Sent: Thursday, November 15, 2018 10:10 AM

To: Constance Truemper; Christopher Unger; David Bonilla; ORA PHARM1 RECALLS

Subject: Request for Conference Call to discuss NDEA

Good Morning Connie,

CDER is requesting a conference call (after 1:00 pm today) to discuss positive findings of NDEA in Mylan Valsartan API. Can you please respond and let me know Teva's availability for today?

Thanks!

Dellarese Herbert, R.N., B.S.N.

Lieutenant Commander, U.S. Public Health Service

U.S. Food & Drug Administration

Division Recall Coordinator/Compliance Officer

Division of Pharmaceutical Quality Operations I & IV

(CT, DC, DE, MA, MD, ME, NH, NJ, NY, PA, RI, VA, VT, WV, AK, AZ, CA, CO, HI, ID, MT, NM, NV, OR, UT, WA, WY)

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"It takes many good deeds to build a good reputation, and only one bad one to lose it"